

EMBOLUS EXTRACTOR

Background of the Invention

The present invention pertains generally to emboli collection and removal.

Blood thrombus, may form a clot in a patient vasculature. Sometimes such clots
5 are harmlessly dissolved in the blood stream. At other times, however, such clots may lodge in a blood vessel where they can partially or completely occlude the flow of blood. If the partially or completely occluded vessel feeds blood to sensitive tissue such as, the brain, lungs or heart, for example, serious tissue damage may result.

When symptoms of an occlusion are apparent, such as an occlusion resulting in a
10 stroke, immediate action should be taken to reduce or eliminate resultant tissue damage. One approach is to treat a patient with clot dissolving drugs. These drugs, however, do not immediately dissolve the clot and may have harmful side effects. Thus, it may be desirable to physically remove the clot from the patient.

Summary of the Invention

The present invention pertains to an improved clot or embolus extractor device and method. Various embodiments of the claimed invention are possible, examples of these embodiments will briefly be described herein and in more detail below in the detailed description of the invention. One embodiment of an embolus extractor in
20 accordance with the invention includes two struts coupled to the distal end of an elongate shaft. In a first collapsed position, the struts are generally disposed parallel to the elongate shaft. In a second expanded position, the proximal end of the struts defines a generally circular mouth disposed at approximately 90° to the length of the elongate

shaft. The portion of the struts extending distally of the mouth defines a generally tapered, for example, cylindrical body with a conical tip. With such a configuration, an emboli mass, such as a cylindrical thrombus may be contained by the embolus extractor.

One embodiment of an embolus extractor in accordance with the present invention includes an elongate shaft having a proximal end and a distal end. The proximal ends and distal ends of first and second struts are coupled to the shaft and allow rotation of the struts around the shaft. A sleeve may be used to slidably couple the distal ends of the struts to the shaft. A sleeve may also be used to slidably couple the proximal ends of the struts to the shaft. The struts can be disposed in a first position and a second position. In the first position, the distal ends and the proximal ends of the struts are spaced at a first distance. In the second position, the distal ends and the proximal ends of the struts are spaced at a second distance, which is less than the first distance.

In the first position struts can be disposed generally parallel and adjacent to the shaft. In the second position, a proximal portion of the first and second struts can define a generally circular mouth. In the second position, the portion of the struts extending generally distally from the mouth, can define a generally distally tapering body. The proximal portion of the struts forming the mouth can extend from the shaft at 45° to 90° to the length of the shaft. This angle could also be between 60° and 90° or between 80° and 90° .

The struts can include a shaped memory metal, such as NiTi alloy. Additional struts can be added to the embolus extractor to enhance the thrombus containing ability of the embolus extractor. These struts may have a smaller cross sectional diameter than the first and second struts.

In accordance with the present invention, an embolus extractor can be advanced through a patient's vasculature in a first compressed position, distally beyond a clot. The embolus extractor can then be deployed in a second expanded position, then drawn proximally to a second compressed position to capture, contain and remove the thrombus to a larger diameter vessel or from the body.

Brief Description of the Drawings

Figure 1 is a prospective view of a first embodiment of an embolus extractor.

Figure 2 is a side view of the embolus extractor of Figure 1.

Figure 3 is a cross sectional view of a micro catheter containing the embolus extractor of Figure 1.

Figure 4 is a cross sectional view of the micro catheter of Figure 2 showing the embolus extractor partially disposed from the micro catheter.

Figure 5 is a cross sectional view of a vessel including a clot and the embolus extractor of Figure 1 disposed in a micro catheter positioned proximally of the clot.

Figure 6 is a cross sectional view of the vessel of Figure 5 showing the micro catheter and embolus extractor traversing the clot.

Figure 7 is a cross sectional view of the vessel of Figure 5 showing the embolus extractor deployed distally of the clot.

Figure 8 is a cross sectional view of the vessel of Figure 5 showing the clot captured by the embolus extractor and the extractor puller locked at the tip of the micro catheter.

Figure 9 is a side view of an alternate embodiment of an embolus extractor.

Figure 10 is a side view of yet an alternate embodiment of an embolus extractor.

Figure 11 is a distal end view of the embolus extractor of Figure 10.

Figure 12 is a side view of yet an alternate embodiment of an embolus extractor.

Figure 13 is a distal end view of the embolus extractor of Figure 12.

5 Figure 14 is a top view of yet another alternate embodiment of an embolus extractor.

Figure 15 is a distal end view of the embolus extractor of Figure 14.

Detailed Description

10 Referring now to the Figures, wherein like referenced numerals refer like elements throughout the several views, Figure 1 is a perspective view of an embolus extractor 10. Embolus extractor 10 includes first and second primary struts 12 and first and second secondary struts 14 coupled to an elongate shaft 16. Struts 12 and 14 can be coupled to shaft 16 at their proximal ends by a sleeve 18 and at their distal ends by a
15 sleeve 20. A spring tip 22 can be disposed at the distal end of shaft 16. Spring tip 22 can be selectively shaped by a physician to guide embolus extractor 10 into micro vessels and stabilize embolus extractor 10 after deployment.

Struts 12 as shown in Figure 1 are disposed in an expanded or delivered position. In this position, a proximal portion 30 extends generally perpendicularly to the length of
20 shaft 16 to form a generally circular mouth. A distal portion 32 of struts 12 extending distally of the mouth generally tapers distally to form a distally tapered body having, for example, a generally conical distal shape. Struts 14 transverse the taper body to enhance the clot catching and holding ability of embolus extractor 10. Struts 12 and 14 can be

made from various materials including shaped memory metals, such as NiTi alloys.

Secondary struts 14 may have a smaller diameter or transverse cross sectional area than primary struts 12.

Elongate shaft 16 can be formed from a material similar to those used for making
5 guide wires, such as plastic polymers, stainless steel, NiTi alloy or other suitable
material. Sleeve 18 can be formed from a wire coil. Adhesive, solder or the like may be
applied to fixally connect the proximal ends of struts 12 and 14 and sleeve 18 to shaft 16
or the proximal bushing. Sleeve 20 can also be formed from a wire coil. Adhesive,
solder or the like can be used to connect struts 12 and 14 to sleeve 20. If struts 12 and 14,
10 are connected to each other, but not fixally connected to shaft 16, sleeve 20 can slide
along shaft 16. Both sleeves 18 and 20 can include a radiopaque material. Struts 12 and
14 can also include radiopaque material to visualize their deployed shape.

Figure 2 is a side view of embolus extractor 10 of Figure 1. In Figure 2 embolus
extractor 10 is also shown in the expanded or deployed position. Proximal portion 30 of
15 struts 12 defining the mouth is shown disposed at Angle A relative to the length of shaft
16. Angle A can be approximately 90°, between 45° and 90°, between 60° and 90°, or
between 80° and 90°. It should be understood that, although Angle A is shown as the
angle between the distal end of shaft 16 and proximal portion 30 of struts 12, Angle A
can also be the angle between portion 30 of struts 12 and the portion of shaft 16 proximal
20 struts 12. Since each strut 12 defining the generally circular mouth can move
independently, the size of the mouth opening can vary. For example, in relatively small
vessels, struts 12 can move closer together to create a smaller mouth; whereas in larger

vessels, struts 12 can expand to create a larger mouth. If for example, NiTi alloy is used to form struts 12 and 14, struts 12 and 14 can have a preset expanded shape.

The length of shaft 16 and the size of the various elements of embolus extractor 10 can be selected with respect to the location in a patient's vasculature to be accessed.

- 5 For example, if a patient's cerebral arteries are to be accessed from a femoral approach, the length of shaft 16 should be sized accordingly. The diameter of the generally circular mouth from the proximal portion 30 of struts 12 can be sized to atraumatically engage the wall of the vessel in which it is deployed. The number of primary and secondary struts may be increased or decreased depending on the size of the vessel and the characteristics
- 10 of the clot.

Figure 3 is a cross sectional view of a micro catheter 24 for embolus extractor 10. Micro catheter 24 can have a radiopaque marker tip 21. Tip 21 can be made from, for example, a platinum band or a polymer loaded with a radiopaque material. As shown in Figure 3, embolus extractor 10 is disposed in a collapsed or delivery position. In this

- 15 position, sleeve 20 has slide distally along shaft 16 to allow struts 12 and 14 to be compressed within micro catheter 24 and be disposed generally parallel to shaft 16.

Figure 4 is a cross sectional view of micro catheter 24 wherein embolus extractor 10 is disposed in part within micro catheter 24 and in part distally of micro catheter 24. Struts 12 and 14 can be biased to self expand as micro catheter 24 is removed.

- 20 Figure 5 is a cross sectional view of a blood vessel 26 which may be, for example, a cerebral artery. A clot 28, including thrombus is shown occluding vessel 26. A micro guidewire 29 has been advanced distally of clot 28. Micro catheter 24 will then also be advanced distally of clot 28.

As shown in Figure 6, micro catheter 24 has been advanced distally of clot 28. Micro guidewire 29 has been removed proximally. Embolus extractor 10 has been placed in micro catheter 24 by an introducer sheath (not shown) at the proximal end of micro catheter 24.

5 As shown in Figure 7, once micro catheter 24 and embolus extractor 10 are advanced at least in part distally of clot 28, embolus extractor 10 may be deployed by further advancing embolus extractor 10 relative to micro catheter 24 such that struts 14 in and 12 are allowed to expand. Alternately, micro catheter 24 can be retracted proximally relative to embolus extractor 10 to allow struts 12 and 14 to expand.

10 As shown in Figure 8, embolus extractor 10 can then be drawn proximally such that struts 14 and 12 engage and capture clot 28. If struts 12 have been configured such that the proximal mouth engages the wall of vessel 26, the mouth portion can act as a separator to release clot 28 from the vessel wall. After clot 28 has been captured by embolus extractor 10, the profile of struts 12 and 14 can be reduced by placing struts 12
15 and 14, at least in part, in micro catheter. If sleeve 18 and tip 21 are radiopaqued, the relative distance that embolus extractor 10 is withdrawn within micro catheter 24 can be observed by fluoroscopy. Clot 28, embolus extractor 10 and micro catheter 24 can then be removed proximally by way of, for example, a guide catheter (not shown).

Figure 9 is a side view of an alternate embodiment of an embolus extractor 110.

20 Embolus extractor 110 can be made from materials, and in an expanded position used in a manner similar to embolus extractor 10. It includes primary struts 112 and secondary struts 114. Primary struts 112 and secondary struts 114 are coupled to elongate shaft 116 at their proximal ends by sleeve 118 and at their distal ends by sleeve 120. In this

embodiment, however, both sleeves 120 and 118 are free to slide along shaft 116.

Proximal movement, however, can be limited by a stop 119 fastened to elongate shaft 116. Distal movement can be limited by spring tip 122. Like shaft 16, shaft 116 can be formed from a wire.

- 5 Shaft 116 can include a polymer coating 121 to improve collapse and repositioning processes of the device. Coating 121 can be polymer tetrafluorine ethylene (PTFE) or other suitable material. Such a coating could be used on any of the shafts described herein.

- 10 A proximal end 130 of struts 112 defines a generally circular mouth. A distal portion 132 of struts 112 can define a generally tapered body portion. The mouth portion of embolus extractor 110 can be disposed at an Angle A to shaft 116 as described above with respect to Angle A and embolus extractor 10.

- Figure 10 describes yet another embodiment of embolus extractor 210 in an expanded position. Embolus extractor 210 can be made from materials, and used in a
15 way similar to that described above with respect to embolus extractor 10. Embolus extractor 210 includes a generally helical strut 210 coupled to an elongate shaft 216 at its proximal end by sleeve 218, and its distal end by sleeve 220. Sleeve 218 or sleeve 220 can be slidable along shaft 216. If both sleeve 218 and sleeve 220 are slidable along shaft 216, it may be desirable in addition to providing spring tip 222, to provide a proximal
20 stop (not shown) proximal sleeve 218.

 A proximal portion 230 of strut 212 can form a generally circular mouth. Distal portion 232 of strut 212 can taper distally to form a tapered body. Portion 230 of strut

212 can be disposed at an Angle A to elongate shaft 216 as described above with respect to Angle A of embolus extractor 10.

Figure 11 is a distal end view of embolus extractor 210 of Figure 10. The generally circular mouth and tapering body of strut 212 can be seen in Figure 11.

5 Figure 12 is a side view of yet another alternate embodiment of an embolus extractor 310 in an expanded position. Embolus extractor 310 can be made from materials, and used in a manner similar to that described above with respect to embolus extractor 10. Embolus extractor 310 includes primary struts 312. Struts 312 can be connected at their proximal end by sleeve 318 to an elongate shaft 316. Struts 312 can be
10 coupled together at their distal ends by sleeve 320.

Proximal end 330 of struts 312 can define a generally circular mouth. Distal portion 332 of struts 312 can taper distally to form a distal body portion. Portion 330 of struts 312 can be disposed at an Angle A to elongate shaft 316 as described above with respect to embolus extractor 10.

15 Figure 13 is a distal end view of embolus extractor 310 of Figure 12. The generally circular mouth and tapered body portion of embolus extractor 310 can be seen in Figure 13.

Figure 14 is a top view of yet another alternate embodiment of an embolus extractor 410 in an expanded position. Embolus extractor 410 can be made from
20 materials similar to, and used in a manner similar to embolus extractor 10 as described above. Embolus extractor 410 includes primary struts 412 and 413. Primary struts 412 and 413 can be coupled to an elongate shaft 416 at their proximal ends by sleeve 418 and at their distal ends by sleeve 420. Sleeve 418 or sleeve 420 can be slidable along shaft

416. It may be desirable, however, if both sleeve 418 and 420 are slidable along shaft 416 to provide a stop proximal sleeve 418. A distal spring tip 422 can act as a distal stop. Proximal portion 430 of primary struts 412 and 413 can form a generally circular mouth. Distal portion 432 of primary struts 412 and 413 can taper distally to form a generally tapered body. A transition between proximal portion 430 and distal portion 432 can occur at bend 442 along primary strut 412 and at bend 443 along primary strut 413.

Figure 15 is a distal end view of embolus extractor 410. The circular mouth and tapered body defined by struts 412 and 413 can be seen in Figure 15. Additionally, it can be seen that strut 413 in part overlaps strut 412.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the invention. The inventor's scope is, of course, defined in the language in which the pending claims are expressed.